CA Clinics

PARTICIPANT INFORMATION STATEMENT

HREC Project Number:	2020-02-174
Full Project Title:	An Open Label Observational of Safety and Efficacy of a Pharmaceutical grade Cannabis Medicine (MediCabilis CBD extract Oil) in Patients undergoing Medicinal Cannabis Therapy for Different Indications
Protocol No:	BOD20201
Sponsor:	BOD Australia Limited
Principal Investigator:	Dr. Ben Jansen
Co-Investigator:	Dr. Crosby Rechtin
Location:	CA Clinics

1. Introduction

You are invited to take part in this research project because you are undergoing medicinal cannabis treatment and you are an adult aged 18 years or over.

This Participant Information Sheet and Consent Form tells you about the research project. It explains the purpose of the research, procedures and risks involved. It also describes information about you that will be obtained, how that information will be used and with whom it will be shared. Knowing what is involved will help you decide if you want to take part in the research. Please read this information carefully. Ask questions about anything that you don't understand or want to know more about. Before deciding whether or not to take part, you might want to talk about it with a relative, friend or your local doctor. Participation in this research is voluntary. If you don't wish to take part, you don't have to. You will receive the best possible care whether or not you take part. If you decide you want to take part in the research project, you will be asked to sign the Consent Form.

By giving your consent to take part in this study you are telling us that you:

- ✓ Understand what you have read.
- ✓ Agree to take part in the research study as outlined below.
- ✓ Agree to the use of your personal and health information as described.

You will be given a copy of a signed and dated of this Participant Information and Consent Form to keep.

2. What is the purpose of this study?

This study involves the collection and analysis of data collected as a part of routine care from patients undergoing medicinal cannabis treatment within Clinics across Australia. Taking part in the study is completely voluntary, and will in no way impact on the treatment you receive by your doctor.

This study will monitor several safety and health-related measures of patients engaged in medicinal cannabis treatment. This will help doctors to gain a better understanding of the role of medicinal cannabis in treating various health conditions and help shape further clinical trials.

It is expected that approximately 500 patients participate in this study. This study will run for 12 months in several clinics across Australia.

3. What does participation in this study involve?

Before you begin the study, you will be given detailed information about the study, and any other relevant information by research staff. You are encouraged to ask questions until you are sure that you fully understand the nature and requirements of the study.

If you decide to be assessed for inclusion in the study, you will be asked to sign a consent form. You should only be asked to participate in this study if your doctor has decided independently to treat your conditions with MediCabilis. In addition you should be diagnosed by your doctor for your condition or disease. **You should agree to abstain from using cannabis products other than MediCabilis for the duration of your participation in this study**.

MediCabilis is an oily solution (to take by mouth) that contains cannabidiol (CBD) in MCT oil.

De-identified data will be collected at your routine visits. The following information are collected:

- You will be asked about your current **health status and about your medical history**, including all **medications**, over-the-counter and herbal medications and supplements that you have been, and are currently taking.
- You will be asked some personal details about yourself, including your date of birth.
- **Questionnaires:** You will be asked questions to assess your responses to how you feel and the effect of the medicine on your quality of life. You may be asked these questions on various visit throughout your participation in the study.

Data will be collected as part of your standard clinical procedure and will not require you to make additional clinic visits. Approximately, nine contacts and/or visits are expected for the duration of this study.

You may be asked to complete some of this information online using a secure system. The completion of these questionnaires take 5 to 10 minutes.

Table below shows the schedule of activities during your treatment period:

Time (Months)	Baseline	2 weeks	1	2	3	4	5	6	12
Informed consent	X								
Demographic data (age, gender)	X								
Medical history, Clinical assessments and diagnoses	X								
Concomitant medications	X		X		X			X	X
MediCabilis administered dose and details related to their treatment plan	X	X	X		X			X	X
Adverse events associated with medicinal cannabis treatment	X	X	X	X	X	X	X	X	X
Questionnaires	X		X	X	X	X	X	X	X

4. Are there risks to me in taking part in this study?

It is possible that you may experience some distress as a result of completing the questionnaires, which ask about sensitive information regarding how you rate your health. You can contact your treating doctor for support.

You are free to choose not to participate in the study and your decision either way will not in any way impact upon or compromise your clinical treatment. If you choose not to continue in the study, only data up to the time you decided to withdraw consent will be used for the study.

Risks of MediCabilis (study drug)

There have not been any previous studies performed on patients who use MediCabilis, however, many clinical studies have been done on its active ingredient (CBD). The clinical studies in humans demonstrate CBD is generally well tolerated and has a good safety profile.
The most commonly experienced adverse effects with CBD are drowsiness (36% or 36 in 100), diarrhea (31% or 31 in 100), decreased appetite (28% or 28 in 100), fatigue (20% or 20 in 100).

The amount of THC (Cannabinoid found in cannabis) in MediCabilis is less than 0.2% (or 2 mg/mL). Thus psychiatric effects are not expected from MediCabilis. Please tell your doctor as soon possible if you notice feeling depressed or disoriented, feeling over-excited or losing touch with reality, have difficulty speaking, eating (more or less than usual), or seeing/hearing things that are not there (hallucinations). Since MediCabilis has some THC, there is a chance that THC could be detected in your Saliva or blood.

Your doctor will collect all adverse events that you experience and report while you are taking MediCabilis. The adverse events that you may experience are nothing to do with your participation in the study and they are merely being data collection to help understanding the safety of MediCabilis.

5. Will I benefit from the study?

As this is an observational study, there will be no personal benefits to you as a result of your participation. However, your participation in this study may help develop important scientific knowledge that could contribute to the development of a new medication and better treatment of patients with similar conditions to yours.

6. What are the alternatives to participation?

Since this study is an observational study, your alternative to being a volunteer in this study is to choose not to participate in the study.

If you decide to take part, you will be given this Participant Information and Consent Form to sign and you will be given a signed copy to keep.

7. What if I don't want to take part in this study, or if I want to withdraw later?'

Participation in this study is voluntary. It is completely up to you if you participate. If you decide not to participate, it will not affect the treatment you receive now, or in the future. Whatever your decision, it will not affect your relationship with any of the Doctors or service staff caring for you. If you wish to withdraw from the study once it has started, you can do so at any time without giving a reason by contacting your doctor or any research staff listed in Section 14.

Participants who cease taking medicinal cannabis following consultation with their doctor will automatically be withdrawn from the study. Note; that participants will remain in the study up until the point of withdrawal. Participant research data will be retained in accordance with standard medical guidelines.

8. How will my confidentiality be protected?'

Your records relating to this study and any other information received will be kept strictly confidential. However staff participating in your care, the sponsor and other agencies authorised by law, may inspect the

records related to the study. In the event you are admitted to hospital as a result of an adverse event resulting from this study, your treating doctor may require access to your study records.

In all cases when dealing with personal information BOD Australia Limited and any of their agents will be required to comply with the Privacy Act 1988. The personal and health information about you that is collected during the course of this study will remain confidential and secure as permitted by applicable laws. All data that is transferred will be coded to prevent identification of individual participants and a participant number will identify you instead of your name. You will not be referred to by name and your personal identity will not be revealed in any report, meeting or publication.

In accordance with relevant Australian and other relevant laws, you have the right to request access to the information collected and stored by the researchers about you. You also have the right to request that any information with which you disagree be corrected. Please contact one of the researchers named at the end of this document if you would like to request to access your information.
Your identity will not be revealed and your confidentiality will be protected in any reviews and reports of this study which may be published. Your treating Doctor/s will be notified of your participation in this study and of any clinically relevant information noted by the trial doctor in the conduct of the trial.

Data from your study medical record will be identifiable and stored in secured offices at the CA Clinics. Only research team members and authorised representatives from the sponsor, the ethics committee or regulatory agencies will have access to your medical records. You have a right to request access and request correction to your information.

Information you provide us will be recorded in special electronic forms and will be coded by your unique study number, and thus will be considered re-identifiable. The information from these forms will be added to a computerised database managed by the sponsor and will be part of the study results, which may be published. This database will be protected by the use of a password.

A copy of these forms and your study medical record will be kept for at least 15 years with all other study related documents.

By signing the consent section, you authorise release of, or access to, this confidential information to the relevant study personnel and regulatory authorities as noted above.

This information will be reviewed by authorised individuals from the contract research organisation, BOD Australia Limited affiliates, contractors and/or Health Authorities or Government Agencies (including the Therapeutic Goods Administration) and delegates of the Bellberry Human Research Ethics Committee for the purpose of confirming the accuracy of the research study data. By signing the consent section, you authorise release of, or access to, this confidential information to the relevant study personnel and regulatory authorities as noted above. Your data will not be transferred overseas.

9. Will taking part in this study cost me anything, and will I be paid?'

Participation in this study will not incur additional costs over and above what you would normally pay for clinical visits, the medication and dispensing/shipping costs. There is no reimbursement for participants.

10. What happens if I suffer injury or complications as a result of the study?

If you suffer any injuries or complications as a result of this study, you should contact the study doctor as soon as possible, who will assist you in arranging appropriate medical treatment. In an emergency you should call **000**. If you feel distressed, you may contact lifeline 24 hours a day on **13 11 14**. You may have a right to take legal action to obtain compensation for any injuries or complications resulting from the study. Compensation

may be available if your injury or complication is caused by the drugs or procedures, or by the negligence of any of the parties involved in the study. If you receive compensation that includes an amount for medical expenses, you will be required to pay for your medical treatment from those compensation monies. If you are not eligible for compensation for your injury or complication under the law, but are eligible for Medicare, then you can receive any medical treatment required for your injury or complication free of charge as a public patient in any Australian public hospital.

11. Could this research be stopped unexpectedly?

This research project may be stopped unexpectedly for a variety of reasons. These may include reasons such as decisions made in the commercial interests of the sponsor or by local regulatory/health authorities.

12. Who is running the study, and how is this study being paid for?'

This study is funded by BOD Australia and conducted at various clinics across Australia. Your doctor is not being paid to participate in this study.

No member of the research team will receive a personal financial benefit from your involvement in this research project (other than their ordinary wages).

13. What happens with the results, and will I be told the results of the study?'

If you give us your permission by signing this consent document, we plan to publish data in scientific journals, present the findings to healthcare professionals and consumers at national and international conferences. In any publication, presentation or public report, information will be provided in such a way that you cannot be identified. However, results may be suppressed for commercial reasons as the sponsor of the project retains the rights to the data.

14. What should I do if I want to discuss this study further before I decide?

When you have read this information, your doctor or a someone from the study team will discuss it with you and any queries you may have. You may wish to take the time to discuss your participation with others (e.g. family, friends, general practitioner) before you decide.
If you have any further questions regarding this study, please do not hesitate to contact Dr. Crosby Rechtin on 1300 991 477 .

What happens if new Information arises during the study?

During the research project, new information about the risks and benefits of the project may become known to the researchers. If this occurs, you will be told about this new information. This new information may mean that you can no longer participate in this research. If this occurs, the person(s) supervising the research will stop your participation. In all cases, you will be offered all available care to suit your needs and medical condition.

15. What if I have a complaint or any concerns about the study?'

Research involving humans in Australia is reviewed by an independent group of people called a Human Research Ethics Committee (HREC). The ethical aspects of this study have been approved by Bellberry HREC. As part of this process, we have agreed to carry out the study according to the National Statement on Ethical Conduct in Human Research (2007) and the Australian Code for the Responsible Conduct of Research.

If you are concerned about the way this study is being conducted or you wish to make a complaint to someone independent from the study, please contact Bellberry on (08) 8361 3222. Please quote the study title and protocol number.

CONSENT FORM

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Location:	CA Clinics

- I am aged 18 years or over.
- I have read the Participant Information Sheet or someone has read it to me in a language that I understand.
- I understand the purposes, procedures and risks of the research described in the project.
- I give permission for my doctors, other health professionals, hospitals or laboratories outside this hospital to release information to the Centre for Clinical Studies concerning my treatment that is needed for this project. I understand that such information will remain confidential.
- I have had an opportunity to ask questions and I am satisfied with the answers I have received.
- I understand that I will be given a signed/dated copy of this document to keep.
- I freely agree to participate in this research project as described and understand that I am free to withdraw at any time during the study without affecting my future health care

Participant's Name (printed) ……

Signature

Date _____/_____/_____ Time _____:_____

Declaration by Study Doctor/Senior Researcher

I have given a verbal explanation of the research project, its procedures and risks and I believe that the participant has understood that explanation.

Researcher's Name (printed) ……

Signature

Date _____/_____/_____ Time _____:_____

A senior member of the research team must provide the explanation of, and information concerning, the research project.

Note: All parties signing the consent section must date their own signature.

REVOCATION OF CONSENT

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I hereby wish to **WITHDRAW** my consent to participate in the study described above and understand that such withdrawal **WILL NOT** in any way effect any treatment or my relationship with my doctor.

Strike out whichever is not applicable:

I do not want any further involvement or follow up in regard to this research project

OR

I agree to be involved for follow up only until the end of the research project.

_____	_____	_____
Signature of participant	**Please PRINT name**	**Date**
_____	_____	_____
Acknowledgment by Investigator	**Please PRINT name**	**Date**